

Chapter I. Introduction

A. Purpose and Organization of Document

The purpose of this document is to provide the Scientific Advisory Panel (SAP) with an overview of the aquatic and terrestrial Level II Refined Risk Assessment (RRA) Models (Version 2.0), a key product of EPA's initiative to refine the ecological risk assessment process. These refined models, which will be presented at an SAP meeting scheduled for March 30 - April 2, 2004, incorporate probabilistic tools and methods that provide information on the probability or likelihood of ecological impact and on the magnitude or severity of the effect resulting from the use of pesticides.

Organized into six chapters, this document begins with an introductory chapter (Chapter I) that provides background information for the SAP meeting. This first chapter describes the purpose and organization of this document, the goals and history of OPP's initiative to refine the ecological risk assessment process, and an overview of the proposed conceptual risk assessment process. The document continues with Chapter II, which describes the purpose of the SAP meeting, presents the charge to the Panel by listing the questions the Agency would like the SAP to address. Chapters III and IV provide an overview of the terrestrial and aquatic Level II Refined Risk Assessment Models (Version 2.0), respectively, focusing on those changes which were made since the models (Version 1.0) were initially presented to the SAP on March 13 - 16, 2001. Lastly, the document ends with conclusions (Chapter V), a bibliography (Chapter VI), and appendices.

B. History and Goals of Initiative

In May 29 - 31, 1996, the Agency presented two ecological risk assessment case studies to the SAP for review and comment. While recognizing and generally reaffirming the utility of EPA's current deterministic assessment process (risk quotient method), the SAP offered a number of suggestions for improvement (FIFRA Scientific Advisory Panel, 1996a and 1996b). Foremost among their suggestions was a recommendation to move beyond the present single point assessment process by developing the tools and methodologies necessary to conduct a probabilistic assessment of effects. Such an assessment would estimate the magnitude and probability of the expected impact and define the level of certainty and variation involved in the estimate.

The recommendations of the SAP were consistent with issues that risk managers within EPA's Office of Pesticide Programs (OPP) have raised, namely questions about the magnitude of the risk described for a particular pesticide, the probability of the risk occurring, and the certainty of the evaluation.

Following the recommendations of the SAP and in response to issues raised by OPP risk managers, the Agency began an initiative to refine the ecological risk assessment process for pesticides. The refined process focuses on evaluating the effects of pesticides to terrestrial and

aquatic species within the context of FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act), the main statutory authority for regulating pesticides at the federal level.

The key goals and objectives of EPA's initiative include the following:

- Develop a conceptual approach to refine the ecological assessment process;
- Incorporate probabilistic tools and methods to provide an estimate on the magnitude and probability of effects;
- Address the broad spectrum of responses to pesticide exposure;
- Reflect more realistic actual use scenarios and field conditions;
- Build upon existing data requirements for registration;
- Utilize, wherever possible, existing data bases and create new ones from existing data sources to minimize the need to generate additional data; and
- Focus additional data requirements on reducing uncertainty in key areas.

The initiative began with the formation of The Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM), composed of experts drawn from government agencies, academia, contract laboratories, environmental advocacy groups, and industry. This Committee was tasked with identifying and developing probabilistic tools and methods for terrestrial and aquatic assessments under the FIFRA regulatory framework. The conclusions and recommendations of the ECOFRAM were summarized in the Draft Aquatic Workgroup Report and the Draft Terrestrial Workgroup Report (ECOFRAM, Terrestrial Workgroup, 1999; ECOFRAM, Aquatic Workgroup, 1999).

After completion of the ECOFRAM draft reports, the Agency held two public workshops to obtain external scientific review and comment on the reports from scientists who had not participated in the developmental process. Participants in the June 22 - 23 and June 23 - 24, 1999 workshops included a broad representation of affiliations and represented the scientific disciplines necessary to conduct a thorough review. The workshop comments, which were factored into the decisions regarding the implementation of the ECOFRAM recommendations, may be accessed through the home page for this initiative.

<http://www.epa.gov/oppefed1/ecorisk/index.htm>

Once the reports and the peer review workshops were completed, the Agency formed the Refined Risk Assessment Implementation Team (Implementation Team), which was charged with developing a plan to incorporate probabilistic tools and methods into the assessment process. After evaluating the ECOFRAM reports and workshop comments, the Implementation Team developed a conceptual approach for implementing changes to the current deterministic assessment process, using the reports and workshop comments as a starting point. This approach, which was evaluated and endorsed by the SAP in 2000 (FIFRA Scientific Advisory Panel, 2000), is based on a four-level risk assessment scheme (U.S. Environmental Protection Agency, 2000a, 2000b, and 2000c) and is described in Chapter I.C. of this document.

After proposing the four-level risk assessment scheme, the Implementation Team focused on developing pilot models (Version 1.0) and on conducting a case study for “ChemX”. On the aquatic side, the refined risk assessment followed the approach outlined in the Agency’s four-level risk assessment scheme for Level II. On the terrestrial side, the refined assessment went beyond the Level II assessment and fell somewhere between a Level II and III. A summary of the case studies reviewed by the SAP is presented in Appendices A and B, and a synopsis of the major SAP comments on the case studies is presented in Chapters III and IV.

Following the case study with ChemX, the Agency refined the models based on the SAP comments made in 2001. In addition, the terrestrial Level II model was also refined to include dermal and inhalation exposure based on recommendations from ECOFRAM. These routes of exposure were also discussed during the SAP meeting held in 2000. These Level II models (Version 2.0), which are presented in Chapters III and IV, are the subject of this SAP session.

C. Overview of Proposed Conceptual Risk Assessment Process

This section provides an overview of the Agency’s proposed conceptual risk assessment process. Although the Agency will not be focusing on the conceptual risk assessment process in this meeting, a summary of the process is presented in this section to help the Panel understand the context of the Level II models within the conceptual framework.

The conceptual risk assessment process is based on four Levels of Refinement, with guidance to assist risk managers in determining when to move to higher levels. Early levels provide more simplistic assessments and use more conservative assumptions, while higher levels include probabilistic tools and methods and provide increasingly realistic biological effects and exposure scenarios. Data requirements, in addition to those currently in place, are focused at each level on those parameters for which there is the least confidence and where uncertainty can only be reduced by the collection of additional data.

The following sections (C.1 and C.2) of this chapter provide an overview of the Levels of Refinement and a discussion of the guidance that is being developed to move from one level to another.

1. Levels of Refinement

The conceptual risk assessment process for both aquatic and terrestrial assessments begins with Level 1, in which effects and exposure data are integrated to evaluate the potential for adverse ecological effects to non-target species. Level I provides a conservative screening level assessment based on the calculation of a risk quotient in which a point estimate of exposure is divided by a point estimate of effects; the magnitude and probability of risk are not evaluated in a Level I assessment. In this assessment, the estimated environmental concentration (EEC), based on maximum application rates and/or rates associated with other label options such as typical uses, is compared to an effects level, such as an acute or chronic toxicity value.

Once the risk quotient is calculated, it is compared to the Agency's Levels of Concern (LOCs). These LOCs provide the Agency with criteria to analyze potential risk to non-target organisms and to consider the need for regulatory action.

The next level of assessment, Level II, provides an initial estimate of the probability and magnitude of effects in vulnerable areas. Although this level provides point estimates for some parameters where little or no data are available for generating probability distributions, reasonable hypothetical distributions of exposure and effects parameters may be established using expert judgment and available published data. These distributions may be largely generic and are not necessarily species- or pesticide-use specific. Examples include distributions of residues on avian food items and metabolism of pesticides within and between soil and water. Through sensitivity analysis, Level II assessments will identify the parameters that provide the greatest contribution to the variability and uncertainty of the assessment's conclusions.

Level III assessments will provide more refined predictions of the probability and magnitude of impacts. They will focus on exposure and effects parameters that contribute the most to the risk assessment uncertainty identified in the sensitivity analysis of the Level II assessment.

Level IV assessments will provide the highest level of refinement. These assessments may include highly specific pesticide use scenarios and may incorporate additional data to establish the spatial and temporal pattern of exposure for species of concern. Additionally, data may be required to reduce the uncertainty associated with using effects data generated in laboratories for test species other than the focal species of concern. These data may include laboratory testing of the focal species themselves and effects testing conducted under actual field conditions of pesticide use.

2. Guidance to Move Between the Levels of Refinement

The Agency believes that an essential component of this risk assessment scheme is clear and publicly available guidance regarding the types of information that need to be considered when moving to a higher level of analysis. The guidance that is being developed will likely consider ecological as well as risk management factors.

On the ecological side, the types of information that could be considered in developing this guidance include the nature of the toxic effect, the likelihood that the effect will occur given the estimated environmental concentrations of the pesticide and its degradates, the uncertainty surrounding the most important variables affecting the predicted risk, and the number and types of organisms potentially affected. From a risk management perspective, examples of what may be considered include the availability of other alternative pesticides and their effectiveness for the same crop/pest combination, ability to potentially mitigate the risk, and the data needed to reduce uncertainties in the estimates of the magnitude and likelihood of the effects given the additional factors required to reach an informed risk/benefit decision.

Until the guidance is developed, though, the Agency will make the decision to move to a higher level of refinement on a case-by-case basis, considering the risk assessment uncertainties and risk management considerations described above.